UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GENENTECH, INC., Plaintiff, v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania non-profit corporation, Defendant.	Case No.: 10-CV-02037-LHK

[TENTATIVE] FINAL JURY INSTRUCTIONS

Dated: June 11, 2012

LUCY H. KOH
United States District Judge

1.6 WHAT IS EVIDENCE

The evidence you are to consider in deciding what the facts are consists of:

1. the sworn testimony of any witness;

2. the exhibits which are received into evidence; and

3. any facts to which the lawyers have agreed.

Source: Ninth Circuit Model Civil Jury Instructions - 1.6 (2007 Edition)

1.7 WHAT IS NOT EVIDENCE

In reaching your verdict, you may consider only the testimony and exhibits received into evidence. Certain things are not evidence, and you may not consider them in deciding what the facts are. I will list them for you:

(1) Arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they have said in their opening statements, will say in their closing arguments, and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of them controls.

(2) Questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection or by the court's ruling on it.

(3) Testimony that has been excluded or stricken, or that you have been instructed to disregard, is not evidence and must not be considered. In addition sometimes testimony and exhibits are received only for a limited purpose; when I give a limiting instruction, you must follow it.

(4) Anything you may have seen or heard when the court was not in session is not evidence. You are to decide the case solely on the evidence received at the trial.

Source: Ninth Circuit Model Civil Jury Instructions - 1.7 (2007 Edition)

1.8 EVIDENCE FOR LIMITED PURPOSE

Some evidence may be admitted for a limited purpose only.

When I instruct you that an item of evidence has been admitted for a limited purpose, you must consider it only for that limited purpose and for no other.

Source: Ninth Circuit Model Civil Jury Instructions - 1.8 (2007 Edition)

1.9 DIRECT OR CIRCUMSTANTIAL EVIDENCE

Evidence may be direct or circumstantial. Direct evidence is direct proof of a fact, such as testimony by a witness about what that witness personally saw or heard or did. Circumstantial evidence is proof of one or more facts from which you could find another fact. You should consider both kinds of evidence. The law makes no distinction between the weight to be given to either direct or circumstantial evidence. It is for you to decide how much weight to give to any evidence.

Source: Ninth Circuit Model Civil Jury Instructions - 1.9 (2007 Edition)

1.11 CREDIBILITY OF WITNESSES

In deciding the facts in this case, you may have to decide which testimony to believe and which testimony not to believe. You may believe everything a witness says, or part of it, or none of it. Proof of a fact does not necessarily depend on the number of witnesses who testify about it.

In considering the testimony of any witness, you may take into account:

(1) the opportunity and ability of the witness to see or hear or know the things testified to;

(2) the witness's memory;

(3) the witness's manner while testifying;

(4) the witness's interest in the outcome of the case and any bias or prejudice;

(5) whether other evidence contradicted the witness's testimony;

(6) the reasonableness of the witness's testimony in light of all the evidence; and

(7) any other factors that bear on believability.

The weight of the evidence as to a fact does not necessarily depend on the number of witnesses who testify about it.

Source: Ninth Circuit Model Civil Jury Instructions - 1.11 (2007 Edition)

1.14 TAKING NOTES

If you wish, you may take notes to help you remember the evidence. If you do take notes, please keep them to yourself until you and your fellow jurors go to the jury room to decide the case. Do not let note-taking distract you. When you leave, your notes should be left in the jury room. No one will read your notes. They will be destroyed at the conclusion of the case.

Whether or not you take notes, you should rely on your own memory of the evidence. Notes are only to assist your memory. You should not be overly influenced by your notes or those of your fellow jurors.

Source: Ninth Circuit Model Civil Jury Instructions - 1.14 (2007 Edition)

2.1 STIPULATED TESTIMONY

The parties have agreed what [*witness*]'s testimony would be if called as a witness. You should consider that testimony in the same way as if it had been given here in court.

Source: Ninth Circuit Model Civil Jury Instructions – 2.1 (2007 Edition)

2.2 STIPULATIONS OF FACT

The parties have agreed to certain facts [to be placed in evidence as Exhibit __] [that will be read to you]. You should therefore treat these facts as having been proved.

Source: Ninth Circuit Model Civil Jury Instructions – 2.2 (2007 Edition)

2.10 USE OF INTERROGATORIES OF A PARTY

Evidence was presented to you in the form of answers of one of the parties to written interrogatories submitted by the other side. These answers were given in writing and under oath, before the actual trial, in response to questions that were submitted in writing under established court procedures. You should consider the answers, insofar as possible, in the same way as if they were made from the witness stand.

Source: Ninth Circuit Model Civil Jury Instructions – 2.10 (2007 Edition)

2.11 EXPERT OPINION

Some witnesses, because of education or experience, are permitted to state opinions and the reasons for those opinions.

Opinion testimony should be judged just like any other testimony. You may accept it or reject it, and give it as much weight as you think it deserves, considering the witness's education and experience, the reasons given for the opinion, and all the other evidence in the case.

Source: Ninth Circuit Model Civil Jury Instructions – 2.11 (2007 Edition)

2.12 CHARTS AND SDUMMARIES NOT RECEIVED IN EVIDENCE

Certain charts and summaries not received in evidence have been shown to you in order to help explain the contents of books, records, documents, or other evidence in the case. They are not themselves evidence or proof of any facts. If they do not correctly reflect the facts or figures shown by the evidence in the case, you should disregard these charts and summaries and determine the facts from the underlying evidence.

Source: Ninth Circuit Model Civil Jury Instructions – 2.12 (2007 Edition)

2.13 CHARTS AND SUMMARIES IN EVIDENCE

Certain charts and summaries have been received into evidence to illustrate information brought out in the trial. Charts and summaries are only as good as the underlying evidence that supports them. You should, therefore, give them only such weight as you think the underlying evidence deserves.

Source: Ninth Circuit Model Civil Jury Instructions – 2.13 (2007 Edition)

3.1 DUTY TO DELIBERATE

When you begin your deliberations, you should elect one member of the jury as your presiding juror. That person will preside over the deliberations and speak for you here in court.

You will then discuss the case with your fellow jurors to reach agreement if you can do so. Your verdict must be unanimous.

Each of you must decide the case for yourself, but you should do so only after you have considered all of the evidence, discussed it fully with the other jurors, and listened to the views of your fellow jurors.

Do not hesitate to change your opinion if the discussion persuades you that you should. Do not come to a decision simply because other jurors think it is right.

It is important that you attempt to reach a unanimous verdict but, of course, only if each of you can do so after having made your own conscientious decision. Do not change an honest belief about the weight and effect of the evidence simply to reach a verdict.

Source: Ninth Circuit Model Civil Jury Instructions – 3.1 (2007 Edition)

3.2 COMMUNICATION WITH COURT

If it becomes necessary during your deliberations to communicate with me, you may send a note through the Bailiff, signed by your presiding juror or by one or more members of the jury. No member of the jury should ever attempt to communicate with me except by a signed writing; I will communicate with any member of the jury on anything concerning the case only in writing, or here in open court. If you send out a question, I will consult with the parties before answering it, which may take some time. You may continue your deliberations while waiting for the answer to any question. Remember that you are not to tell anyone—including me—how the jury stands, numerically or otherwise, until after you have reached a unanimous verdict or have been discharged. Do not disclose any vote count in any note to the court.

Source: Ninth Circuit Model Civil Jury Instructions – 3.2 (2007 Edition)

3.3 RETURN OF VERDICT

A verdict form has been prepared for you. After you have reached unanimous agreement on a verdict, your presiding juror will fill in the form that has been given to you, sign and date it, and advise the court that you are ready to return to the courtroom.

Source: Ninth Circuit Model Civil Jury Instructions – 3.3 (2007 Edition)

6. SUMMARY OF CONTENTIONS

I will first give you a summary of each side's contentions in this case. I will then tell you what each side must prove to win on each of its contentions. As I previously told you, the University seeks money damages from Genentech for allegedly actively inducing infringement of the claims of the '752 patent by others. The University alleges that the method of administering Herceptin to specific classes of patients under the "Adjuvant Treatment, Breast Cancer" indications in the FDA-approved package insert infringes a method covered by claims 1, 5, 6, 7, 9, 10, 12, 14, 15, 16, 17 of the '752 patent. These are the asserted claims of the '752 patent.

Genentech denies that it has infringed the asserted claims of the patent and argues that, in addition, claims 1, 5, 6, 7, 9, 10, 12, 14, 15, 16 and 17 are invalid.

Your job is to decide whether the asserted claims of the '752 patent have been infringed and whether any of the asserted claims of the '752 patent are invalid. If you decide that any claim of the patent has been infringed and is not invalid, you will then need to decide any money damages to be awarded to the University to compensate it for the infringement. You will also need to make a finding as to whether the infringement was willful. If you decide that any infringement was willful, that decision should not affect any damage award you make. I will take willfulness into account later.

Source:

N.D. Cal. Model Instructions, B.1.

7. INTERPRETATION OF CLAIMS

Before you decide whether Genentech has induced others to infringe the claims of the patent or whether the claims are invalid, you will need to understand the patent claims. As I mentioned, the patent claims are numbered sentences at the end of the patent that describe the boundaries of the patent's protection. It is my job as judge to explain to you the meaning of any language in the claims that needs interpretation.

I have interpreted the meaning of some of the language in the patent claims involved in this case. You must accept those interpretations as correct. My interpretation of the language should not be taken as an indication that I have a view regarding the issues of infringement and invalidity. The decisions regarding infringement and invalidity are yours to make.

The '752 patent uses specific terms in its claims such as "breast cancer cells" and "breast cells" that I have interpreted. The fact that you or anyone may use or have heard in your daily life a different meaning of these terms is not relevant to infringement and validity. You must apply my interpretation of these terms.

"Breast cancer cells"

Claim 1 of the '752 patent contains the phrase "breast cancer cells." The phrase "breast cancer cells" means cells from the breast that have malignant form and structure, the ability for uncontrolled growth, and the potential or ability to invade or metastasize. This definition is how a person of ordinary skill in the art in 1994 would define "breast cancer cells." This definition does not require that a cell have the present characteristic of uncontrolled growth in order to be a "breast cancer cell." Some of the criteria for malignant form and structure that doctors consider include things like high nucleus-to-cytoplasmic ratio, hyperchromasia, nuclear pleomorphism, and disorganization—but not all four criteria are required to have a finding of malignant form and structure

"Breast cells that overexpress p185"

Claim 1 of the '752 patent contains the phrase "breast cells that overexpress p185." This phrase means cells, the origin of which is breast tissue, that overexpress p185 and are not breast cancer cells.

"An individual in need of such inhibition"

Claim 1 of the '752 patent contains the phrase "an individual in need of such inhibition." This phrase means an individual who (i) has a family history of neu-associated breast cancer or a genetic predisposition to neu-associated breast cancer but who has not developed neu-associated breast cancer; or (ii) has had her/his neu-associated breast cancer tumors removed by surgical resection, or has been diagnosed as having neu-associated breast cancer enter remission.

"To down regulate the overexpressed p185"

Claim 1 of the '752 patent contains the phrase "to down regulate the overexpressed p185." This phrase means to decrease the ability of the overexpressed p185 receptors to participate in their

function, by means other than antibody dependent cellular cytotoxicity (ADCC) or complement-mediated cytotoxicity (CDC).

Antibody Produced By Cell Line ATCC Deposit No. 104943

Claim 1 of the '752 patent contains the phrase "antibody produced by cell line ATCC Deposition No. 104943." This phrase means "an antibody 7.16.4 produced by the hybridoma cell line deposited in the America Type Culture Collection and having accession number HB 10493."

"The antibody has the complimentary determining regions from an antibody produced by cell line ATCC Deposit No. HB104943"

Claim 2 of the '752 patent contains the phrase "antibody has the complimentary determining regions from an antibody produced by cell line ATCC Deposit No. HB104943." This phrase means "the antibody has the same amino acid sequences as found in each of the hypervariable regions of the heave and light chains of the 7.16.4 antibody."

The antibody has the variable regions from an antibody produced by cell line ATCC Deposit No. HB104943"

Claim 3 of the '752 patent contains the phrase "antibody has the variable regions from an antibody produced by cell line ATCC Deposit No. HB104943." This phrase means "the antibody has the same amino acid sequences as found in the approximately 110-115 amino acids located at the terminus of the heavy and light chains of the 7.16.4 antibody."

"Antibody with complimentary determining regions from the antibody produced by ATCC Deposit No. HB104943"

Claim 6 of the '752 patent contains the phrase "antibody with complimentary determining regions from the antibody produced by ATCC Deposit No. HB104943." This phrase means the antibody has the same amino acid sequences as found in at least one of the hypervariable regions of the heavy and light chains of the 7.16.4 antibody.

"Antibody with variable regions from the antibody produced by ATCC Deposit No. HB104943"

Claim 7 of the '752 patent contains the phrase "antibody with complimentary determining regions from the antibody produced by ATCC Deposit No. HB104943." This phrase means "the antibody has the same amino acid sequences as found in the approximately 110-115 amino acids located at the N terminus of at least one of the heavy or light chains of the 7.16.4 antibody."

Source:

N.D. Cal. Model Patent Jury Instr. B.2.1. Order Construing Disputed Claim Terms of U.S. Patent No. 6,733,752 (Dkt. 214).

8. INFRINGEMENT – BURDEN OF PROOF

I will now instruct you on the rules you must follow in deciding whether the University has proven that Genentech induced infringement of one or more of the asserted claims of the '752 patent. To prove that Genentech induced infringement of each of the asserted claims of the '752 patent, the University must persuade you both that it is more likely than not that someone else, those who administer Herceptin, directly infringed that claim, and that it is more likely than not that Genentech induced that infringement. I will explain the concepts of direct infringement and inducing infringement in a moment.

Source:

N.D. Cal. Model Patent Jury Instr. B.3.1.

9. DIRECT INFRINGEMENT

A patent's claims define what is covered by the patent. A method directly infringes a patent if it is covered by at least one claim of the patent.

Deciding whether a claim has been directly infringed is a two-step process. The first step is to decide the meaning of the patent claim. I have already made this decision, and I have already instructed you as to the meaning of the asserted patent claims. The second step is to decide whether those who administer Herceptin adjuvant therapy have used, sold, or offered for sale within the United States a method covered by a claim of the '752 patent. If so, it infringes. You, the jury, make this decision.

With one exception, you must consider each of the asserted claims of the patent individually, and decide whether any administration of Herceptin infringes that claim. The one exception to considering claims individually concerns dependent claims. A dependent claim includes all of the requirements of a particular independent claim, plus additional requirements of its own. As a result, if you find that an independent claim is not infringed, you must also find that its dependent claims are not infringed. On the other hand, if you find that an independent claim has been infringed, you must still separately decide whether the additional requirements of its dependent claims have also been infringed.

Whether or not those who administered the drug knew that Herceptin adjuvant therapy infringed or even knew of the patent does not matter in determining direct infringement.

There are two ways in which a patent claim may be directly infringed. A claim may be "literally" infringed, or it may be infringed under the "doctrine of equivalents." The following instructions will provide more detail on these two types of direct infringement.

Source:

N.D. Cal. Model Patent Jury Instr. B.3.2; *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc) ("patent infringement is a strict liability offense")

10. LITERAL INFRINGEMENT

To decide whether a third party used a method that literally infringes any of the asserted claims of the '752 patent, you must compare that method with the patent claim and determine whether every requirement of the claim is included in that method. If so, the third party's method literally infringes that claim. If, however, the third party used a method that does not satisfy every requirement in the patent claim, then the third party's method does not literally infringe that claim. You must decide literal infringement for each asserted claim separately.

If the patent claim uses the term "comprising," that patent claim is to be understood as an open claim. The patent claims in the '752 patent are to be understood as open claims. An open claim is infringed as long as every requirement in the claim is present in the accused method. The fact that the accused method also includes other steps will not avoid infringement, as long as it has every requirement in the patent claim.

Source:

N.D. Cal. Model Patent Jury Instr. B.3.3.

11. INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

If you decide that administering Herceptin adjuvant therapy does not literally infringe an asserted patent claim, you must then decide whether that method infringes the asserted claim under what is called the "doctrine of equivalents."

Under the doctrine of equivalents, the method can infringe an asserted patent claim if it includes steps that are identical or equivalent to the requirements of the claim. If the method is missing an identical or equivalent step to even one requirement of the asserted patent claim, the method cannot infringe the claim under the doctrine of equivalents. Thus, in making your decision under the doctrine of equivalents, you must look at each individual requirement of the asserted patent claim and decide whether the method has either an identical or equivalent step to that individual claim requirement.

A step of a method is equivalent to a requirement of an asserted claim if a person of ordinary skill in the field would think that the differences between the step and the requirement were not substantial as of the time of the alleged infringement.

Changes in technique or improvements made possible by technology developed after the patent application is filed may still be equivalent for the purposes of the doctrine of equivalents if it still meets the other requirements of the doctrine of equivalents set forth in this instruction.

One way to decide whether any difference between a requirement of an asserted claim and a step of the method is not substantial is to consider whether, as of the time of the alleged infringement, the step of the method performed substantially the same function, in substantially the same way, to achieve substantially the same result as the requirement in the patent claim.

In deciding whether any difference between a claim requirement and the method is not substantial, you may consider whether, at the time of the alleged infringement, persons of ordinary skill in the field would have known of the interchangeability of the step with the claimed requirement. The known interchangeability between the claim requirement and the step of the method is not necessary to find infringement under the doctrine of equivalents. However, known interchangeability may support a conclusion that the difference between the step in the method and the claim requirement is not substantial. The fact that a step of the method performs the same function as the claim requirement is not, by itself, sufficient to show known interchangeability.

You may not use the doctrine of equivalents to find infringement if you find that administering Herceptin adjuvant therapy is the same as what was in the prior art before the application for the '752 patent or what would have been obvious to persons of ordinary skill in the field in light of what was in the prior art. A patent holder may not obtain, under the doctrine of equivalents, protection that it could not have lawfully obtained from the Patent and Trademark Office.

Source:

N.D. Cal. Model Instructions, B.3.4

12. INDUCING PATENT INFRINGEMENT

The University argues that Genentech has actively induced another to infringe the asserted claims of the '752 patent. In order for there to be inducement of infringement by Genentech, someone else must directly infringe an asserted claim of the '752 patent; if there is no direct infringement by anyone, there can be no induced infringement. In order to be liable for inducement of infringement, Genentech must:

1. have intentionally taken action that actually induced direct infringement by another;

2. have been aware of the '752 patent; and

3. have known that the acts it was causing would be infringing.

If Genentech did not know of the existence of the patent or that the acts it was inducing were infringing, it cannot be liable for inducement unless it actually believed that it was highly probable its actions would encourage infringement of a patent and it took intentional acts to avoid learning the truth. It is not enough that Genentech was merely indifferent to the possibility that it might encourage infringement of a patent. Nor is it enough that Genentech took a risk that was substantial and unjustified.

If you find that Genentech was aware of the patent, but believed that the acts it encouraged did not infringe that patent, or that the patent was invalid, Genentech cannot be liable for inducement.

Source:

N.D. Cal. Model Patent Jury Instr. B.3.9. *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2067 (2011*); Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 & n.2 (Fed. Cir. 2009); *ACCO Brands, Inc. v. ABA Locks Mfrs.* Co., Ltd., 501 F.3d 1307, 1313 (Fed. Cir. 2007); *DSU Med. Corp. v. JMS Co.*, Ltd., 471 F.3d 1293, 1305 (Fed. Cir. 2006) (*en banc*).

13. WILLFUL INFRINGEMENT

In this case, the University argues that Genentech willfully infringed the University's patent.

To prove willful infringement, the University must first persuade you that Genentech induced infringement of a valid claim of the University's patent. The requirements for proving such infringement were discussed in my prior instructions.

In addition, to prove willful infringement, the University must persuade you that it is highly probable that prior to May 11, 2010, Genentech acted with reckless disregard of the claims of the University's patent.

To demonstrate such "reckless disregard," the University must satisfy a two-part test. The first part of the test is objective. The University must persuade you that Genentech acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. The state of mind of Genentech is not relevant to this inquiry. Rather, the appropriate inquiry is whether the defenses put forth by Genentech fail to raise any substantial question with regard to infringement or validity. Only if you conclude that the defenses fail to raise any substantial question with regard to infringement or validity do you need to consider the second part of the test.

The second part of the test does depend on the state of mind of Genentech. The University must persuade you that Genentech actually knew, or it was so obvious that Genentech should have known, that its actions constituted infringement of a valid patent.

In deciding whether Genentech acted with reckless disregard for the University's patent, you should consider all of the facts surrounding the alleged infringement including, but not limited to, the following factors.

Factors that may be considered as evidence that Genentech was not willful include:

(1) Whether Genentech acted in a manner consistent with the standards of commerce for its industry.

Factors that may be considered as evidence that Genentech was willful include:

(1) Whether Genentech intentionally copied a product or method of the University covered by the patent.

Source:

N.D. Cal. Model Instructions, B.3.10.

14. INVALIDITY – BURDEN OF PROOF

I will now instruct you on the rules you must follow in deciding whether Genentech has proven that claims 1, 5, 9, 10, 12, 14, 15, 16 and 17 of the '752 patent are invalid. Before discussing the specific rules, I want to remind you about the standard of proof that applies to this defense. To prove invalidity of any patent claim, Genentech must persuade you that it is highly probable that the claim is invalid.

During this case, Genentech has submitted evidence, including but not limited to prior art, that was not considered by the United States Patent and Trademark Office (PTO) during the prosecution of the '752 patent. Genentech contends that such evidence invalidates certain claims of the '752 patent. In deciding the issue of invalidity, you may take into account the fact that the prior art was not considered by the PTO when it issued the '752 patent. Prior art that differs from the prior art considered by the PTO may carry more weight than the prior art that was considered and may make Genentech's burden of showing that it is highly probable that a patent claim is invalid easier to sustain.

Source:

N.D. Cal. Model Patent Jury Instr. B.4.1.

15. WRITTEN DESCRIPTION REQUIREMENT

A patent claim is invalid if the patent does not contain an adequate written description of the claimed invention. The purpose of this written description requirement is to demonstrate that the inventor was in possession of the invention at the time the application for the patent was filed, even though the claims may have been changed or new claims added since that time. The application that resulted in the '752 patent was filed on March 30, 1994. The written description requirement is satisfied if a person of ordinary skill in the field reading the original patent application at the time it was filed would have recognized that the patent application described the invention as claimed, even though the description may not use the exact words found in the claim. A requirement in a claim need not be specifically disclosed in the patent application as originally filed if a person of ordinary skill would understand that the missing requirement is necessarily implied in the patent application as originally filed.

Source:

N.D. Cal. Model Patent Jury Instr. B.4.2a

16. ENABLEMENT

A patent claim is invalid if the patent at the time it was originally filed did not contain a description of the claimed invention that is sufficiently full and clear to enable a person of ordinary skill in the field at the time to make and use the full scope of the invention. This is known as the "enablement" requirement.

The patent may be enabling even though it does not expressly state some information if a person of ordinary skill in the field could make and use the invention without having to do excessive experimentation. In determining whether excessive experimentation is required, you may consider the following factors:

- the scope of the claimed invention;
- the amount of guidance presented in the patent;
- the amount of experimentation necessary;
- the time and cost of any necessary experimentation;
- how routine any necessary experimentation is in the field of cancer biology, pathology, and immunotherapy;
- whether the patent discloses specific working examples of the claimed invention;
- the nature and predictability of the field; and
- the level of ordinary skill in the field of cancer biology, pathology, and immunotherapy.

The question of whether a patent is enabling is judged as of the date the original application for the patent was first filed. In this case, the application that resulted in the '752 patent was filed on March 30, 1994.

Source:

N.D. Cal. Model Patent Jury Instr. B.4.2b

17. ANTICIPATION

A patent claim is invalid if the claimed invention is not new. For the claim to be invalid because it is not new, all of its requirements must have existed in a single device or method that predates the claimed invention, or must have been described in a single previous publication or patent that predates the claimed invention. In patent law, these previous devices, methods, publications or patents are called "prior art references." If a patent claim is not new, we say it is "anticipated" by a prior art reference.

The description in the written reference does not have to be in the same words as the claim, but all of the requirements of the claim must be there, either stated or necessarily implied, so that someone of ordinary skill in the field of cancer biology, pathology, and/or immunotherapy looking at that one reference would be able to make and use the claimed invention.

Here is a list of the ways that Genentech can show that a patent claim was not new:

If the claimed invention was already publicly known or publicly used by others in the United States before March 30, 1994.

If the claimed invention was already patented or described in a printed publication anywhere in the world before March 30, 1994. A reference is a "printed publication" if it is accessible to those interested in the field, even if it is difficult to find.

If the claimed invention was already made by someone else in the United States before March 30, 1994 if that other person had not abandoned the invention or kept it secret.

If the claimed invention was already described in another issued U.S. patent or published U.S. patent application that was based on a patent application filed before March 30, 1994;

If Drs. Drebin, Greene and Katsumata did not invent the claimed invention but instead learned of the claimed invention from someone else;

Source:

N.D. Cal. Model Instructions, B.4.3a1

18. OBVIOUSNESS

Not all innovations are patentable. A patent claim is invalid if the claimed invention would have been obvious to a person of ordinary skill in the field at the time the application was filed, which in this case was March 30, 1994. The court, however, is charged with the responsibility of making the determination as to whether a patent claim was obvious based upon your determination of several factual questions.

First, you must decide the level of ordinary skill in the field that someone would have had at the time the claimed invention was made. In deciding the level of ordinary skill, you should consider all the evidence introduced at trial, including:

(1) the levels of education and experience of persons working in the field;

(2) the types of problems encountered in the field; and

(3) the sophistication of the technology.

The University and Genentech agree that the level of education and experience of those working in the field is a person with at least an MD or PhD in the areas of pathology, oncology, and/or immunology with 3-4 years of post-MD or post-PhD experience.

Second, you must decide the scope and content of the prior art. The University and Genentech disagree as to whether [identify prior art reference(s)] should be included in the prior art you use to decide the validity of claims [ ] of the '752 patent. In order to be considered as prior art to the '752 patent, these references must be reasonably related to the claimed invention of that patent. A reference is reasonably related if it is in the same field as the claimed invention or is from another field to which a person of ordinary skill in the field would look to solve a known problem.

Third, you must decide what difference, if any, existed between the claimed invention and the prior art.

Finally, you must determine which, if any, of the following factors have been established by the evidence:

(1) commercial success of a product due to the merits of the claimed invention;

(2) a long felt need for the solution provided by the claimed invention;

(3) unsuccessful attempts by others to find the solution provided by the claimed invention;

(4) copying of the claimed invention by others;

(5) unexpected and superior results from the claimed invention;

(6) acceptance by others of the claimed invention as shown by praise from others in the field or from the licensing of the claimed invention;

(7) independent invention of the claimed invention by others before or at about the same time as the named inventor thought of it, which in this case is March 30, 1994; and

(8) other evidence tending to show obviousness.

Source:

N.D. Cal. Model Instructions, B.4.3b (Alternative 1)

19. DAMAGES – BURDEN OF PROOF

I will instruct you about the measure of damages. By instructing you on damages, I am not suggesting which party should win on any issue. If you find that Genentech induced infringement of any valid claim of the '752 patent, you must then determine the amount of money damages to be awarded to the University to compensate it for the infringement.

The amount of those damages must be adequate to compensate the University for the infringement. A damages award should put the patent holder in approximately the financial position it would have been in had the infringement not occurred, but in no event may the damages award be less than a reasonable royalty. You should keep in mind that the damages you award are meant to compensate the patent holder and not to punish an infringer.

The University has the burden to persuade you of the amount of its damages. You should award only those damages that the University more likely than not suffered. While the University is not required to prove its damages with mathematical precision, it must prove them with reasonable certainty. The University is not entitled to damages that are remote or speculative.

Source:

N.D. Cal. Model Patent Jury Instr. B.5.

20. REASONABLY ROYALTY – DEFINITION

A royalty is a payment made to a patent holder in exchange for the right to make, use or sell the claimed invention. This right is called a "license." A reasonable royalty is the payment for the license that would have resulted from a hypothetical negotiation between the patent holder and the infringer taking place at the time when the infringing activity first began. In considering the nature of this negotiation, you must assume that the patent holder and the infringer would have acted reasonably and would have entered into a license agreement. You must also assume that both parties believed the patent was valid and infringed. Your role is to determine what the result of that negotiation would have been. The test for damages is what royalty would have resulted from the hypothetical negotiation and not simply what either party would have preferred.

A royalty can be calculated in several different ways and it is for you to determine which way is the most appropriate based on the evidence you have heard. One way to calculate a royalty is to determine what is called an "ongoing royalty." To calculate an ongoing royalty, you must first determine the "base," that is, the product on which the infringer is to pay. You then need to multiply the revenue the infringer obtained from that base by the "rate" or percentage that you find would have resulted from the hypothetical negotiation. For example, if the patent covers a nail, and the nail sells for $1, and the licensee sold 200 nails, the base revenue would be $200. If the rate you find would have resulted from the hypothetical negotiation is 1%, then the royalty would be $2, or the rate of .01 times the base revenue of $200.

If the patent covers only part of the product that the infringer sells, then the base would normally be only that feature or component. For example, if you find that for a $100 car, the patented feature is the tires which sell for $5, the base revenue would be $5. However, in a circumstance in which the patented feature is the reason customers buy the whole product, the base revenue could be the value of the whole product. Even if the patented feature is not the reason for customer demand, the value of the whole product could be used if, for example, the value of the patented feature could not be separated out from the value of the whole product. In such a case, however, the rate resulting from the hypothetical negotiation would be a lower rate because it is being applied to the value of the whole product and the patented feature is not the reason for the customer's purchase of the whole product.

A second way to calculate a royalty is to determine a one-time lump sum payment that the infringer would have paid at the time of the hypothetical negotiation for a license covering all sales of the licensed product both past and future. This differs from payment of an ongoing royalty because, with an ongoing royalty, the licensee pays based on the revenue of actual licensed products it sells. When a one-time lump sum is paid, the infringer pays a single price for a license covering both past and future infringing sales.

It is up to you, based on the evidence, to decide what type of royalty is appropriate in this case.

Source:

N.D. Cal. Model Patent Jury Instr. B.5.7.

21. REASONABLE ROYALTY – RELEVANT FACTORS

In determining the reasonable royalty, you should consider all the facts known and available to the parties at the time the infringement began. Some of the kinds of factors that you may consider in making your determination are:

(1) The royalties received by the patentee for the licensing of the patent-in-suit, proving or tending to prove an established royalty.
(2) The rates paid by the licensee for the use of other patents comparable to the patent-in-suit.
(3) The nature and scope of the license, as exclusive or nonexclusive, or as restricted or nonrestricted in terms of territory or with respect to whom the manufactured product may be sold.
(4) The licensor's established policy and marketing program to maintain his or her patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.
(5) The commercial relationship between the licensor and licensee, such as whether they are competitors in the same territory in the same line of business, or whether they are inventor and promoter.
(6) The effect of selling the patented specialty in promoting sales of other products of the licensee, the existing value of the invention to the licensor as a generator of sales of his nonpatented items, and the extent of such derivative or convoyed sales.
(7) The duration of the patent and the term of the license.
(8) The established profitability of the product made under the patents, its commercial success, and its current popularity.
(9) The utility and advantages of the patented property over the old modes or devices, if any, that had been used for working out similar results.
(10) The nature of the patented invention, the character of the commercial embodiment of it as owned and produced by the licensor, and the benefits to those who have used the invention.
(11) The extent to which the infringer has made use of the invention and any evidence probative of the value of that use.
(12) The portion of the profit or of the selling price that may be customary in the particular business or in comparable business to allow for the use of the invention or analogous inventions.
(13) The portion of the realizable profits that should be credited to the invention as distinguished from nonpatented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
(14) The opinion and testimony of qualified experts.
(15) The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

No one factor is dispositive and you can and should consider the evidence that has been presented to you in this case on each of these factors. You may also consider any other factors which in your mind would have increased or decreased the royalty the infringer would have been willing to pay

and the patent holder would have been willing to accept, acting as normally prudent business people. The final factor establishes the framework which you should use in determining a reasonable royalty, that is, the payment that would have resulted from a negotiation between the patent holder and the infringer taking place at a time prior to when the infringement began.

Source:

Federal Circuit Bar Association Model Patent Jury Instr. B.6.7.

22. DATE OF COMMENCEMENT

In the event you find that the asserted claims of the '752 patent are valid and infringed, the damages that the University may be awarded by you commence on November 16, 2006. You cannot assess damages for any sales of Herceptin prior to this date.

Genentech argues that an alternative date for commencement of damages was January 18, 2008.

Source:

N.D. Cal. Model Patent Jury Instr. B.5.8.

23. CALCULATING DAMAGES IN CASES OF INDUCEMENT

In order to recover damages for induced infringement, the University must either prove that administering Herceptin adjuvant therapy necessarily infringes the '752 patent or prove acts of direct infringement by others that were induced by Genentech. Because the amount of damages for induced infringement is limited by the number of instances of direct infringement, the University must further prove the number of direct acts of infringement of the '752 patent, for example, by showing individual acts of direct infringement or by showing that a particular method of administering Herceptin adjuvant therapy necessarily directly infringes.

Source:

N.D. Cal. Model Patent Jury Instr. B.5.9; *ACCO Brands, Inc. v. ABA Locks Mfrs*. Co., Ltd., 501 F.3d 1307, 1313 (Fed. Cir. 2007).